

## REMARKS

Applicant has added new method claims 12-15 to track pending system claims 4, 5, 11 and 8, respectively, in order to round out the scope of protection of the claims in this application and has amended claim 8 to correct inadvertent errors in terminology introduced in the Supplemental Preliminary Amendment filed August 12, 2004. These amendments do not introduce new matter and should be entered. Since the Examiner has already examined method claim 7, the Examiner should examine the new method claims in this application as well.

Claims 7 and 8 stand rejected as anticipated by Berry. The Examiner construes Berry as disclosing an implant method and system for installing different prostheses having different extents, radii of curvature and effective hinge centers and ranging in size from small to large. The Examiner also states that Berry anticipates these claims in part because “[t]he approximate hinge and prostheses dimensions, e.g., hinge radius of an affected part, are determined by tomography and the prostheses are accordingly sized and implanted to accommodate individual anatomy (col. 4, lines 19-23).” This rejection and its supporting reasoning are respectfully traversed.

As applicant has previously explained, independent claim 7 is a method claim that calls for the steps of “determining the hinge radius of an affected joint” and “selecting a prosthesis with a hinge radius approximating the hinge radius of the affected joint.” Berry discloses the performance of neither of these steps. The portion of Berry cited by the Examiner says not a word about the hinge radius of the vertebrae in question, but instead refers in very general terms to “the exact size of the implant 11.” The drawings in Berry do not show hinge radii, nor is there a word in Berry about either measuring hinge radii or of matching the prostheses chosen to the hinge radii of the vertebrae in question. Although applicant’s invention is elegantly simple, Berry says nothing that puts it in possession of a person of ordinary skill in the art, who would see nothing in Berry that instructs him or her to carry out the claimed steps of measuring a hinge radius and selecting a prosthesis to fit the measured hinge radius.

The Examiner has supported the logic in the previous Action by stating on page 4 of the pending Action, "With respect to claim 7, it is noted that Berry does disclose the claimed method, albeit not with the same language as Applicant." With all due respect to the Examiner, what language does Berry use to disclose applicant's claimed method? The disclosures in columns 4 and 9 of Berry contain nothing regarding determining radii of curvature or hinge radii or selecting particular radii or relationships of radii. As applicant points out at page 4, lines 17-20, of the specification, "The hinge radius is defined independently of the slide surface radius and differs from the latter in that it is measured from the center 18 of the hinge movement to the geometric midpoint of the prosthesis." The language in Berry to which the Examiner *does* refer in the Action does not disclose the claimed method, either in the same or in different language.

Perhaps the Examiner is saying that Berry inherently anticipates claim 7, in that practicing what Berry discloses will *necessarily and inevitably* result in performing the method of claim 7. If that is the case, applicant respectfully submits that the Examiner has failed to provide a reasoned basis in fact for a finding of inherency.

The passages in Berry referred to by the Examiner do not recognize achieving the claimed relationship of radii at all. Instead they state that the "size" of the implant is determined based on tomography without referring to hinge radii or the radii of curvature of the hinge surfaces. "Size" refers to external dimensions of the implant and not to choosing the radii of curvature as required by the claimed method. Certainly, there is no evidence that the size of an implant is related to or controlled by the hinge radius. The specification of Berry fails to disclose in any way that the radii of curvature of the hinge surfaces 29, 43 have any correlation to the hinge radii of the involved vertebrae or of performing any step of selection in relation thereto. In fact, the radii of curvature of the surfaces 29, 43 shown in Berry's figures seem to be quite a bit smaller than the hinge radii of the involved vertebrae, which shows that Berry itself does not practice the tomographic sizing of the implant asserted by the Examiner. In FIG. 9, furthermore, Berry discloses an embodiment having two articular joints in which the upper joint has its center

of articulation somewhere below the prosthesis and the lower joint has its center of articulation above the prosthesis. Claim 7 does not relate to such an embodiment at all. The references in Berry to determining the size of the implant by tomography thus do not constitute disclosures or suggestions of how to choose the radii as claimed .

The Examiner's burden under MPEP 2112.IV. is *not* to show that practicing Berry *may* produce the claimed invention; it is the Examiner's burden to explain how following Berry's disclosure *necessarily* produces the claimed method. The Examiner has not provided such reasoning because Berry does not support it. Thus, there is no basis in fact for reasonably believing that following Berry's disclosure will inherently produce the method of claim 7. For these reasons, Berry does not identically disclose the method of the invention as claimed in claim 7.

System claim 8 specifically requires a set of at least two different intervertebral disk prostheses in which the prostheses closer to the head of the subject into which they are to be implanted ("in a cranial direction" in the words of claim 8) have hinge radii that are greater than the hinge radii of the prostheses that are relatively toward the base of the spine ("in a direction more caudal" in the words of claim 8). Berry discloses the opposite of what applicant claims, as can be seen from Berry's Fig. 12 and the supporting disclosure. Fig. 12 unmistakably shows the radii of curvature of the hinge surfaces increasing as one proceeds down the spine in the caudal direction. This increase in radii, contrary to the claimed invention, is also illustrated at col. 8, line 18 – col. 9, line 8, of Berry: In the C1-C3 section R2, the hinge radius of curvature, is 0.188 inches, in the C4-C7 section R2 is 0.219 inches and in the L1-L5 section, R2 is 0.4375 inches. Furthermore, Berry does not correlate hinge radii or radii of curvature to the overall dimensions of the implants.

The Examiner argues that claim 8 sets forth statements of intended use that do not define structure different from what Berry discloses. The Examiner seems to think that all claim 8 defines is two prostheses of different sizes. That is not so. The claimed system includes at least

two different prostheses, it is true, but they differ in characteristics that do not flow from size *per se* but exist independently of mere size, the hinge radii and radii of curvature of the slide surfaces. Applicant's prostheses are different in structural respects that Berry does not disclose, either expressly or inherently. As a result, Berry not only fails to disclose the invention of claim 8, it implicitly teaches away from it.

Claims 4, 5 and 11 stand rejected under 35 USC 103(a) on Berry alone. The Examiner asserts that it would have been obvious to choose the claimed dimensions "since it has been held that where the general conditions of a claim are disclosed in the prior art, i.e., sliding joint prostheses of different sizes, discovering the optimum or workable ranges of the same involves only routine skill in the art." This rejection and its supporting reasoning are respectfully traversed.

As stated in applicant's prior response, this rejection suffers from two crucial defects.

First, it relies on the disclosures in Berry that allegedly support the anticipation rejection of base claim 8, which applicant has already shown Berry does not provide. For that reason alone, the rejection is untenable.

Second, it assumes what the "general conditions" of the claims are, contrary to the requirement that the subject matter of the claimed invention as a whole must be evaluated for obviousness over the prior art. In this case, one of the key features of the invention which Berry does not even hint at is the need to measure the hinge radii of the affected vertebrae so that the surgeon may choose appropriate hinge radii for the different prostheses of the claimed system. There is nothing in Berry which suggests in any way either that the hinge radii of the vertebrae are related to the selection of the prostheses or that, based on such a selection, the hinge radii should relate to the location along the spine as claimed.

Applicant also notes with respect to claim 4 that Berry says nothing that would suggest that selecting any particular slide surface radii, let alone slide radii of greater and less than 18 mm, has any relationship to the performance of the prosthesis system. Thus, it is incorrect to

reject claim 4, or any of the other claims relating to specific radii, claims 5, 12 and 13, on the ground that "discovering the optimum or workable ranges of [the general conditions of the prior art] involves only routine skill in the art." In this record, there is no evidence at all that persons of ordinary skill in the art would have had any reason to choose or optimize radii of slide surface curvature as claimed.

Early action allowing claims 4, 5, 7, 8 and 11-15 in this application is solicited.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing Docket No. **246472006000**.

Respectfully submitted,

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By: 

Barry E. Bretschneider  
Registration No. 28,055

Morrison & Foerster LLP  
1650 Tysons Boulevard  
Suite 300  
McLean, Virginia 22102  
Telephone: (703) 760-7743  
Facsimile: (703) 760-7777